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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,823	11/07/2005	Robert K. Yang	1199-13 PCT/US	2398

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
05/11/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,823	YANG ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *11-15,18 and 21-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10, 16, 17, 19 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response to Non-Final Office Action and Applicant's Arguments/Remarks, all filed 02/01/10 is acknowledged.

Applicant has overcome the following rejection(s) by virtue of persuasive remarks: (1) The 35 U.S.C. §103(a) rejection of claims 1-10, 16, 17, 19 and 20 over Yang et al. (USPN 7,425,292) has been withdrawn.

Claims 1-28 are pending in this action. No amendments to the claims have been made herein. Claims 11-15, 18 and 21-28 remain withdrawn (based on nonelected invention). Claims 1-10, 16, 17 and 19-20 have been examined in this action. Claims 1-10, 16, 17 and 19-20 remain rejected.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-7, 16, 17, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cremer et al. (USPN 6,655,112).

Cremer et al. teaches a primary packaging unit for film-like or wafer-like administration forms for oral application in that a plurality of dosage units are individually sealed and are present in a primary packaging unit and there are perforations between the compartments which enable the separation of the individual compartments (see Abstract); (col. 1, lines 44-55); (col. 3, line 55 – col. 4, line 47). The unit includes therapy patterns by means of printing. Thus, for example, the packaging unit can be a 7-day package with seven dosage units of a drug to be taken once a day (col. 4, lines 55-65).

Cremer meets the edible film as claimed based upon the same features and elements. Thus, Cremer renders the instant invention prima facie obvious to one of ordinary skill in the art.

* * * * *

Claims 1-10, 16, 17, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (WO 00/42992).

Chen et al. teaches a dosage unit comprising a water-soluble hydrocolloid and a mucosal surface-coat forming film, including an effective dose of active agent (see Abstract). The devices of Chen include a heat sealed single pouch, a multi-unit blister card, multi-unit dispensing pack and a perforated film strip and a single dose film (p. 6, lines 4-8). Although Chen does not teach the inclusion of voids, they do teach that the surface area can be adjusted based on various factors (p. 6, line 30 - p. 7, line 10). Also see page 16 of Chen.

Chen meets the edible film as claimed based upon the same features and elements. Thus, Chen renders the instant invention prima facie obvious to one of ordinary skill in the art.

* * * * *

Response to Arguments

Applicant's arguments filed 02/01/10 have been fully considered and were found to be partially persuasive.

- **35 U.S.C. §103(a) rejection over Yang et al. (USPN 7,425,292):**

Applicant argued, "Applicants respectfully submit that Yang et al. is disqualified under 35 U.S.C. § 103(c) as prior art in a rejection under 35 U.S.C. §103(a). MPEP §706.02(1)(2) states that "[i]n order to be disqualified as prior art under 35 U.S.C. 103(c), the subject matter which would otherwise be prior art to the claimed invention and the claimed invention must be commonly owned, or subject to an obligation of assignment to a same person, at the time the claimed invention was made ...." MPEP §706.02(1)(2). As stated in the "Statement Regarding Common Ownership" being filed concurrently herewith, to the best of the undersigned's knowledge, the present application (i.e., U.S. Application No. 10/521,823) and U.S. Application No. 10/074,272 (which issued as U.S. Patent No. 7,425,292 to Yang et al.) were commonly owned, or under an obligation of assignment to the same entity, at the time that the claimed invention of the present application was made."

This argument was found persuasive. Accordingly, the 35 U.S.C. §103(a) rejection of claims 1-10, 16, 17, 19 and 20 over Yang et al. (USPN 7,425,292) has been withdrawn.

- **35 U.S.C. §103(a) rejection over Cremer et al. (USPN 6,655,112):**

Applicant argued, "Cremer teaches away from a film which includes multiple dosage units. Cremer discloses individually sealed dosage units having perforations between the compartments which enable separation of the individual compartments, whereby the perforations are within a packaging material and not within the film itself."

Applicant's arguments have been fully considered but were not held persuasive. It is agreed that the Cremer's dosage units are individually sealed and compartmentalized, whereby the perforations occur in the packaging and not the film. However, there is nothing in the instant claims that would exclude the individually sealed or packaged dosage units disclosed by Cremer. Furthermore, the instant claim language does not exclude the "single" dosage units of Cremer. Note that the instant claims merely recite "dosage units". Thus, Applicant's arguments do not establish the scope of claims presented, which clearly permit the use of a sealed or individually-packaged (single) dosage units.

This rejection has been maintained.

- **35 U.S.C. §103(a) rejection over Chen et al. (WO 00/42992):**

Applicant argued, "The perforated film strip 19 of Chen is not a film including dosage units which are releasably joined by one or more weakened sections which permit the dosage units to be detached from the film. Moreover, Chen is directed to overcoming problems attendant delivery of active agents in solid form via the mouth and has absolutely nothing to do with providing films which have weakened sections which permit the dosage units to be detached from the film."

Applicant's arguments have been fully considered but were not deemed persuasive. In response to applicant's argument that "Chen is not a film including dosage units which are releasably joined by one or more weakened sections which permit the dosage units to be detached from the film", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably

distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The limitation of "releasably joined....which permit the dosage units to be detached from the film" denotes a future-intended use limitation which does not accord patentable weight to the claims.

With respect to Applicant's argument that Chen is directed to distinct problems than that of the instant invention has been considered but was not found convincing. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. See, e.g., In re Kahn, 441 F.3d 977, 987, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). ("One of ordinary skill in the art need not see the identical problem addressed in a prior art reference to be motivated to apply its teachings."); In re Linter, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). It is the position of the Examiner that the prior art vividly teaches a product as claimed herein, having the structural elements and features (i.e., perforated dosage units) as presently claimed.

This rejection has been maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday-Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

hns

May 10, 2010